K051670

MAR 3 0 2006

1. 510(k) Summary

Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2580 Matheson Blvd. E.
Mississauga, Ontario L4W 4J1
Canada

C. Company Phone: (905) 602-4875 ext 252

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar
Regulatory Affairs Manager

F. Summary Prepared on: 28-Mar-2006

Device Identification

A. Device Trade Name: RF Tunneler Wire

B. Device Common Name: Tunneler Wire

C. Classification Name: Wire, guide, catheter

D. Device Class: Class II (per 21 CFR 870.1330)

E. Device Code: DQX

Identification of Predicate Devices

Predicate devices are the Baylis Medical RF Perforation Probe (Baylis Medical Company Inc.), which is cleared under 510(k) Premarket Notification number K010265; the Safe-Cross Radio Frequency Total Occlusion Crossing System (IntraLuminal Therapeutics Inc.), which is cleared under 510(k) Premarket Notification number K031842; and the CLiRpath Excimer Laser Catheter (Spectranetics Corp.), which is cleared under 510(k) Premarket Notification number K040067.

Device Description

The RF Tunneler Wire consists of a core wire surrounded with a polymer insulation. The wire connects to a perforation generator at the proximal end via a connector cable, and has an active tip at the distal end to delivery RF energy.

The RF Tunneler Wire is designed to be compatible with most balloon and stent catheters approved for use in peripheral interventional procedures.

Intended Use

The RF Tunneler Wire is intended to create a channel in totally occluded peripheral vessels 3 mm or greater.

Comparison to Predicate Devices

The RF Tunneler Wire is similar to the Baylis Medical RF Perforation Probe in design and function. The intended use of the RF Tunneler Wire is substantially equivalent to the Safe-Cross Radio Frequency Total Occlusion Crossing System and the CLiRpath Excimer Laser Catheter in intended use.

The RF Tunneler Wire and the predicate devices are all wires used in interventional procedures. They all focus energy at the active tip to create channels in target tissue.

Biocompatibility, Sterilization, Packaging, and Bench Testing

Biocompatibility of the materials used in the RF Tunneler Wire has been tested and confirmed to verify compliance with safety requirements. Sterilization of the RF Tunneler Wire has been validated. Packaging of the RF Tunneler Wire has been validated.

The RF Tunneler Wire has undergone mechanical and electrical bench testing to verify compliance with safety and performance requirements. These tests include comparing the RF Tunneler Wire to a predicate device.

Conclusion

Testing of the RF Tunneler Wire verified the safety and performance characteristics of this device for its intended use. The functions of the RF Tunneler Wire, as well as its performance characteristics as verified in bench testing are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Baylis Medical Company
c/o Meghal Khakhar, MBBS, CerRAP, RAC
Regulatory Affairs Manager
2580 Matheson Blvd. E
Mississauga, ON L4W 4J1
CANADA

SEP 18 2013

Re: K051670
Trade/Device Name: Baylis RF Tunneler Wire
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: March 22, 2006
Received: March 24, 2006

Dear Ms. Khakhar:

This letter corrects our substantially equivalent letter of March 30, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051670

Device Name: Baylis RF Tunneler Wire

Indications For Use:

The RF Tunneler Wire is intended to create a channel in totally occluded peripheral vessels 3 mm or greater.

Prescription Use [X] AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051670